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Attorney Docket No. 8465-43
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Lasse W. Mogensen et al.	:	
Serial No.: 10/813,214	:	Confirmation No.: 5131
Filed: March 29, 2004	:	Group Art Unit: 3767
For: INJECTOR DEVICE FOR PLACING A SUBCUTANEOUS INFUSION SET	:	Examiner: Elizabeth Moulton

REPLY BRIEF

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Sir:

In accordance with 37 C.F.R. § 41.41, Appellants file this Reply Brief within two months from the date of the Examiner's Answer of November 12, 2009, regarding the above-mentioned patent application.

A. STATUS OF THE CLAIMS

The statement of the status of the claims contained in the Examiner's Answer is incorrect. Claims 70 and 71 were inadvertently omitted from the listing of the claims. A correct statement of the status of the claims is as follows and should replace the statement made in Section III of Appellants' Appeal Brief filed on August 3, 2009:

This appeal involves claims 50, 52, 53, 56, 58, 66, 67, 69-72, 78, 79, 82-88 and 90-92.

Claims 60-64 and 93-100 are allowed.[1]

Claims 51, 54, 55, 57, 59, 65, 68, 73-77, 80, 81, and 89 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.[2]

B. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Please replace the grounds of rejection at Section VI of Appellants' Appeal Brief with the following three grounds of rejection presented for review:

1) the rejection of claims 50, 56, 67, 69-72, 78, 82-88 and 90-92 under 35 U.S.C. § 102(b) as being anticipated by Miskinyar, U.S. Patent No. 5,527,287[3];

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[1] The rejections of claims 93-100 have been withdrawn and the claims have been allowed per pages 2 and 3 of the Examiner's Answer.

[2] The rejections of claims 51, 54, 55, 57, 59, 65, 68, 80, 81 and 89 have been withdrawn and the claims have been indicated to contain allowable subject matter per pages 2 and 3 of the Examiner's Answer. It is noted that claim 87 is included both in the listing of the claims involved in the appeal on page 2 and on page 3 of the Examiner's Answer in the listing of the claims where the rejection has been withdrawn. Appellants confirmed with the Examiner by telephone on January 7, 2010 that claim 87 stands rejected and is involved in the appeal.

[3] It is noted that the "Evidence Relied Upon" section at page 3 of the Examiner's Answer lists U.S. Patent No. 4,894,054 to Miskinyar while paragraph 1 of section (9) at page 3 of the Examiner's Answer presents a rejection based on U.S. Patent No. 5,527,287 to

2) the rejection of claim 58 under 35 U.S.C. § 103(b) as being obvious in view of Miskinyar and Teeple, Jr., U.S. Patent No. 5,807,316; and

3) the rejection of claims 52, 53, 66, 78 and 79 under 35 U.S.C. § 103(b) as being obvious in view of Safabash et al., U.S. Patent No. 6,293,925 and Miskinyar.

C. ARGUMENT

(1) Miskinyar does not teach a removable insertion set.

At page 5 in section (10) A.1.a. of the Examiner's Answer mailed November 12, 2009 ("the Examiner's Answer"), the Examiner asserts "there is nothing in the claims about the needle or cannula remaining in the patient or even being removable once inside the patient." The Examiner is correct that the claims are silent about such matters. As pointed out at pages 26 and 27 of Appellants' Appeal Brief, there is no suggestion in Miskinyar to cut off its hypodermic needle 22.

In fact, Miskinyar teaches disposing the device after use and using the protective cover 38 for **totally enclosing** the needle 22. (Miskinyar, Col. 4, lines 33-37 and Col. 6, lines 45-48.) In addition, a special advantage of the invention according to Miskinyar is that the device is very safe, such that there is no possibility of passing a contagious or infectious disease such as AIDS or other HIV viruses. (Miskinyar, Col. 8, ll. 8-11.) One of skill in the medical arts would clearly interpret the term "said insertion set being separable from said plunger" as recited in independent claim 50, to NOT include a needle that is cut off.

Yet, that is what the Examiner suggests when she modifies Miskinyar in an effort to anticipate the claimed insertion set having a housing and cannula. Nowhere does Miskinyar teach that its needle is intended to be cut from the syringe or that its ampoule is separable from the ampoule chamber. Nonetheless, the Examiner alters the intended purpose of the needle 22 of Miskinyar "by cutting" it from the housing.

Miskinyar. Since the Office Action of April 22, 2009 relied on the '287 patent to reject the claims, Appellants will treat the reference to the '054 patent in the "Evidence Relied Upon" section as being made in error.

According to the Examiner, since the needle 22 can be cut, it is capable of being removed and thus is a removable cannula. The Examiner cannot cite to any case where a reference had been modified from its intended purpose in order to prove anticipation. Further, since both hypodermic needle 22 and ampoule 74 are not separable from ampoule member 18, Miskinyar does not disclose an insertion set that is separable from a plunger as recited in claim 50.

(2) Miskinyar does not teach a cover having through-flow sterilization properties.

At page 6 in section (10)A.1.b. and at page 7 in section (10)A.1.h. of the Examiner's Answer, the Examiner asserts that the tape 72 of Miskinyar is capable of allowing through-flow of a sterilizing agent. The Examiner cites to Figure 2 and Col. 8, lines 50-60 of Miskinyar for support of the assertion. Appellants disagree. A review of Figure 2 fails to reveal any through-flow property for tape 72. Regarding the passage relied on by the Examiner it states the following:

> All of the component parts of the injection device can be fabricated of readily available materials such as plastics using injection molding techniques for mass production. The device can be marketed with significantly lower costs than conventional automatic syringes. The device can be assembled and pre-loaded with measured amounts of medication under sterile conditions by the pharmaceutical supply house and can be sealed with the frangible sterile tape and the protective overlay tape, isolating the medication from contact with the external environment. (Col. 8, ll. 50-60).

The above passage is silent as to tape 72 having a through-flow property. Indeed, Miskinyar teaches away from such a property since the device is assembled under sterile conditions and then sealed with sterile tape 72 which is permanently bonded to the housing. (Miskinyar, Col. 4, lines 1-2 and Col. 8, lines 55-60.) If the tape 72 had a flow-through property it would not necessarily seal the device so as to isolate "the medication from contact with the external environment" (Col. 8, ll. 58-60). Clearly, Miskinyar fails to teach a releasable cover allowing through-flow of a sterilizing agent as recited by Appellants' claims 71 and 88.

(3) Miskinyar does not teach a deformable housing.

At page 7 in section (10)A.1.c. of the Examiner's Answer, the Examiner asserts "the housing (as a whole) changes shape or deforms." The assertion has no merit.

As described in Appellants' specification at paragraph 43, "release of the plunger 30 may be caused by pressing manually on diametrically opposed outside areas of the device housing 28 to deform the housing 28 and thereby effect release of the trigger arms 38." Such pressing causes the shape of the housing 28 to change. Such a definition is supported by the dictionary (Merriam-Webster's Collegiate Dictionary, Tenth Edition, 1998, p. 303), wherein the term "deformable" is defined to mean "to alter the shape of by stress" or "to become misshapen or changed in shape" or "distort." The plain meaning of the term "deform" is very different from translationally moving a button from one position to another where the button itself does not change shape. Clearly, the button 33 of Miskinyar that moves up and down as asserted by the Examiner does not result in a change in shape or form of the button 33 of Miskinyar in a manner as required by the housing recited in claims 72, 78, 86 and 87. Miskinyar clearly does not teach or suggest that any part of the device is "deformable."

(4) Miskinyar does not teach manual engagement areas.

At page 7 in sections (10)A.1.d.-g. of the Examiner's Answer, the Examiner asserts that the sides or the top of the button, or any surface of the button of Miskinyar is a manual engagement area and that the button may be pushed at both sides to deploy the plunger. This assertion is incorrect. Appellants' claim 82 recites manual engagement areas for the manual deformation of the housing. Claims 83-85 depend from claim 82. Claim 82 depends directly from claim 72 and as discussed above, Miskinyar does not teach or suggest that any part of the device is "deformable." In addition, the button 33 of Miskinyar supports, on its undersurface, a knife 42 with a circular blade and cutting edges 66 that is aligned with plastic ring 56 so that it will puncture the plastic ring and discharge the pressured air into the ampoule chamber to inject the medication into the patient. (*See* Col. 3, ll. 30-42.) In other words, the button 33 must be pressed downward in the direction of the patient

so that the knife 42 can release the air and cause injection of the medication. Pressing on diametrically opposed manual engagement areas (recited in claim 83) or manual engagement areas offset by about 90° (recited in claim 84) on the button 33 of Miskinyar does not deform the button 33 and does not cause the button 33 to move downward toward the patient as required for operation of the Miskinyar device. Miskinyar clearly does not teach or suggest that the housing includes manual engagement areas for the manual deformation of the housing as recited in claim 82 or the diametrically opposed or offset manual engagement areas as recited in claims 83 and 84.

(5) Miskinyar does not teach sterilizing an insertion set by flowing a sterilizing agent through a membrane.

At page 7 in section (10)A.1.i. of the Examiner's Answer, the Examiner asserts that the tape 72 allows for the sterile air to pass through the open area below the ampoule and thus meets the limitation of "allowing through-flow" of a sterilizing agent (sterile air) into said device housing. This assertion is incorrect.

Appellants' claim 90 recites "sterilizing said insertion set by flowing a sterilizing agent through said membrane into an interior of said injector device housing." Miskinyar does not disclose such sterilization. Miskinyar does not disclose any type of sterilizing agent or sterilizing an insertion set by flowing the sterilizing agent through a membrane. Miskinyar simply refers to assembly and pre-loading of medication under sterile conditions and application of the tape to isolate the medication from contact with the external environment. (Miskinyar, Col. 8, ll. 56-60.) Clearly, Miskinyar fails to disclose sterilizing an insertion set by flowing a sterilizing agent through the membrane into an interior of the injector device housing as required by claims 90-92.

(6) The combination of Miskinyar and Teeple Jr. does not teach assuring the sterile condition of the removable insertion set or indicia relating to shelf life of the assembly.

At page 8 in section (10)B.1. of the Examiner's Answer, the Examiner asserts that Miskinyar alone teaches assuring sterile conditions of the infusion set. The

Examiner also asserts that the shelf life in the claims is not limited to the sterile shelf life of the device and that it would be obvious to list the shelf life of the drug so that an expired or degraded drug is not delivered to the patient.

Claim 58 depends from claim 50 and as discussed above in section C.(1) of Appellants' Reply Brief, Miskinyar does not teach the claimed removable insertion set. While it is true that the shelf life in claim 58 is not limited to the device, the Examiner's assertion ignores the recitation in claim 58 requiring "indicia relating to the shelf life **of the assembly**." The Examiner does not explain how the bar code and bar code reader for tracking expired anesthetic drugs can be used for indicia relating to the shelf life of the injector device assembly. Clearly, Miskinyar and Teeple Jr., together and individually, fail to teach or suggest a sterile removable insertion set and indicia relating to the shelf life of the injector device assembly as recited in claim 58.

D. CONCLUSION

For at least these reasons and all other reasons set forth above and in the Appellants' opening brief, the rejections of claims 50, 52, 53, 56, 58, 66, 67, 69-72, 78, 79, 82-88 and 90-92, as well as the objection to claims 51, 54, 55, 57, 59, 65, 68, 73-77, 80, 81, and 89, should be **REVERSED** and all of those claims allowed.

Respectfully submitted,

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